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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/036,053	03/06/98	EPPSTEIN	J 19141.0001

QM32/0413
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EXAMINER	
BOCKELMAN, M	
ART UNIT	PAPER NUMBER
3763	12

DATE MAILED: 04/13/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Best Available Copy

Office Action Summary

Application No.	Applicant(s)
09/036,053	Eppstein
Examiner	**Group Art Unit**
Bockelman	3763

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 1-14-2000.

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle,* 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1-21, 29, 32-48 is/are pending in the application.

Of the above claim(s) 32-43 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-21, 44-48 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachment(s)

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11

☐ Interview Summary, PTO-413

☒ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The such that clause at the end of claim 48 does not make sense.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

3. Claims 1-3, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al 3,964,482.

Gerstel teaches a device that microporates the skin using probes 12 , flux enhancers 48-64 and diuretics (column 14 line 9) as one of the many drugs.

4. Claims 1, 3, 8-9, 13, 17-18, 21, 29, 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al USPN 5,947,921.

Johnson teaches the mixing of electroporation, ultrasound and flux enhancers to both deliver drugs as well as extract analytes which can also include suction (column 9 line 1-11) as well as inflammatory mediators in the form of corticosteroids.

5. Claims 1-21, 29, 44 -48 are rejected under 35 U.S.C. 102(e) as being anticpated by Eppstein et al Eppstein teaches the invention as claimed including the use of a heated probe and flux enhancers see claims 35 and 38.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claim 1-3, 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerstel et al 3,964,482 in view of Sibalis 5,328,453.

Gerstel teaches a device that microporates the skin using probes 12 , flux enhancers 48-64 and diuretics (column 14 line 9) as one of the many drugs. While the flux

enhancers of Gerstel are primarily to overcome the resistance of the outer membrane, it would have been obvious to have delivered a vasodilator to increase flux to the bloodstream beneath the skin.

8. Claims 1, 3, 8-9, 13, 17-18, 21, 29, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al USPN 5,947,921 in view of Sibalis 5,328,453.

Johnson teaches the mixing of electroporation, ultrasound and flux enhancers to both deliver drugs as well as extract analytes which can also include suction (column 9 line 1-11) as well as inflammatory mediators in the form of corticosteroids. While Johnson et al teaches enhancers that definetly act at the membrane barrier, Sibalis teaches the use of vasodilators for enhancng flux to the bloodstream. To have used vasodilators for systemic delivery in Johnson would have been obvious.

9. Claims 2, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. USPN 5,947,921 (alone or in combination with Siabalis) in view of Gerstel USPN 3,964,482 and Lee et al USPN 5,250,023. Applicant differs from Johnson et al. in reciting a probe that is heated to carry the flux enhancer. Gerstel shows that it was known to deliver flux enhancers as carried by microprobes 12 to help penetrate the stratum corneum. To have provided the Johnson et al device with such structure for similar reasons would have been obvious. Without specifying a datum point, all probes are considered heated.

10. Claims 4-6, 14-15 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al USPN 5,947,923 (alone or in view of Sibalis) in view of Bettinger USPN 5,427,585.

Applicant differs from Johnson in providing a heating element to heat the treatment site. Bettinger shows such a device to pretreat the skin for enhanced delivery. To have provided Johnson with the heating device of Bettinger for similar reasons would have been obvious. It is noted that the ethanol that Johnson et al uses is known to vaporize at room temperature. The added heat from resistance heating would cause even faster vaporization.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1-21, 29 and 44-48 are rejected under the judicially created doctrine of double patenting over claims 1-66 of U. S. Patent No.5,885,211 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: Each of the sets of claims teaches a methof of microporation along with the use of chemical penetration enhancers. The claims differ only in scope , yet the use of the term "comprising" creates overlap and multiple coverages to the preferred embodiments.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

13. Applicant's arguments filed 1-14-2000 have been fully considered but they are not persuasive. Applicant's claims state that the permeation enhancers act at or beneath the outer membrane. The flux enhancers known in the iontophoretic art and suggested by Gerstel and Johnson act at least in the outer layer. Applicant's arguments seem to focus on events under the outer layer yet the claims are broader as noted. In addition the examiner has provided new, alternative grounds of rejections that render applicant's arguments moot.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Bockelman whose telephone number is (703) 308-2112. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood-Coggins, can be reached at (703) 308-1344. The main fax phone number for this Group is (703) 305-3590. Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0858.

MWB

April 10, 2000

MARK BOCKELMAN
PRIMARY EXAMINER